

Remarks

Claims 24-39 and 44 are pending in the subject application. Applicants acknowledge that claims 27, 33, 38 and 39 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 25, 27 and 31-36, amended claims 24, 28, 29, 30, 37, 38 and 44 and added new claims 45-49. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see original claims 1-23 of PCT/EP2004/052572 and pages 8, 22 and 25-26 of the as-filed specification). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 24, 26, 28-30, 37 and 44-49 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claims 26, 28, 29, 34, 35 and 44 are free of the prior art.

The Examiner notes that the listing of references at pages 46 and 47 in the specification is not a proper form for an Information Disclosure Statement (IDS). Applicants submitted Information Disclosure Statements in the subject application on March 28, 2006, October 3, 2007 and March 9, 2009 and the Examiner has acknowledged her consideration of this IDS in the instant Action. Applicants acknowledge that only those references submitted in these IDSes or cited on form PTO-892 have been considered by the Examiner.

The subject specification has been objected to on the grounds that it does not comply with 37 CFR §1.821 through 1.825 and Figures 1 and 7B are objected to because they depict sequences without identifying the sequences by SEQ ID NO. Applicants respectfully submit that the brief description of Figure 1 on page 6, lines 12-16, of the as-filed specification is identified with SEQ ID NOS. 1-4. By this Amendment, Applicants have amended the brief description of Figure 7B to include the sequence identifier number. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claim 24 is objected to because of informalities. The Examiner indicates that the term "variant result" should be "variant results". Applicants gratefully acknowledge the Examiner's careful review of the claims. In view of the cancellation of this phrase, it is respectfully submitted that this issue is now moot. Accordingly, reconsideration and withdrawal of the objection is

respectfully requested.

Claims 29 and 35 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claim 29 (a) was previously drawn to a method “wherein said monomeric variant contains, in the corresponding sequence of SEQ ID NO: 2 and SEQ 10 NO: 4: a) a Cysteine in position 8, 14, 17, or 77;” As noted in the Office Action, both SEQ ID NOs: 2 and 4 are polypeptides that are 76 amino acids in length. Applicants thank the Examiner for her careful review of the claims and submit that this issue is now moot in view of the revisions made to claim 29 and the cancellation of claim 35. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 24-26, 28-32, 34-37 and 44 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action indicates that the specification is enabled for a method for treating an autoimmune or inflammatory disease wherein MCP-1 signaling is involved in the disease process, comprising the administration of an effective amount of a monomeric variant of a homodimer-forming chemokine, wherein said variant is SEQ ID NO:2, or SEQ ID NO:4 or wherein said monomeric variant contains, in the corresponding sequence of SEQ ID NO: 2 and SEQ ID NO: 4: a) a Cysteine in position 8, 14, or 17 or an additional cysteine at the C-terminus of SEQ ID NOs 2 or 4 or b) an alanine or a glycine in position 1 (as recited in Claim 29) or wherein said variant comprises SEQ ID NO:2, or SEQ ID NO:4 or a variant which contains, in the corresponding sequence of SEQ ID NO: 2 and SEQ ID NO: 4: a) a cysteine in position 8, 14, or 17 or an additional cysteine at the C-terminus of said sequences or b) an alanine or a glycine in position 1 and a constant region of a human immunoglobulin heavy chain, it is not enabled for a method of preventing any autoimmune, inflammatory, or infectious disease or a method of treating any infectious disease or a method of treating any, unspecified autoimmune or inflammatory disease comprising administration of any unspecified variant of any homodimer forming chemokine. Applicants respectfully assert that the claims as filed are enabled. However, in accordance with the suggestion of the Examiner, the claims have been amended in a manner that attends to the issues noted in the Office Action. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 24, 25, 28, 29-31, and 3437 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully submit that the amendment of claim 24 has rendered this issue moot and respectfully request reconsideration and withdrawal of the rejection.

Claims 24, 25, 36 and 37 are rejected under 35 U.S.C. § 102(b) as anticipated by Rollins *et al.* (U.S. Patent No. 5,705,360). The Office Action argues that the '360 patent teaches a method of treatment comprising administration of a mutant chemokine to a patient for treatment of a chemokine mediated disease such as inflammation or an autoimmune disease (column 6, lines 55-59). The Office Action further argues that the reference teaches administration of an MCP-1 (CCI.2) derivative (column 7, lines 29-30) and that the mutated MCP-1 derivative may be the 7ND derivative. This derivative corresponds to the MCP-1 peptide with deletions of amino acids 2 to 7 at the N-terminus (column 3, lines 31-33).

It is well settled that in order for the Patent Office to establish a *prima facie* case of anticipation, each and every element of the claimed invention, arranged as required by the claim, must be found in a single prior art reference, either expressly or under the principles of inherency. See generally *In re Schreiber*, 128 F.3d 1473, 1477; *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677-78 (Fed. Cir. 1988); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). In this case, it is respectfully submitted that Rollins *et al.* fails to anticipate the claimed invention because it fails to teach the claimed polypeptides and their use for the treatment of autoimmune or inflammatory diseases. Applicants respectfully assert that the Rollins *et al.* reference does not anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claims 30 and 31 are rejected under 35 U.S.C. § 103(a) as obvious over Rollins *et al.* (U.S. Patent No. 5,705,360) in view of Herrmann *et al.* (U.S. Patent No. 6,100,387). Applicants respectfully assert that the claimed invention is not obvious over the cited references.

It is fundamental patent law that an obviousness rejection fails if the prior art relied on does not disclose all of the limitations of the claimed invention. See, e.g., *In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001). Thus, obviousness requires a teaching or suggestion of all limitations in a

claim. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). As noted above, Rollins *et al.* fails to teach the claimed polypeptides and their use for the treatment of autoimmune or inflammatory diseases. Herrmann *et al.* fails to remedy this defect in the teachings of Rollins *et al.* Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested because a *prima facie* case of obviousness has not been established by the combined teachings of the references.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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